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March 30, 2001

please deliver immediately

Facsimile Transmission

10 pages including this page

Minh Tam
Art Unit 1642
Fax No: 703-308-4426
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cc:

RE: U.S. Patent Application No. 09/030,606
Your Reference:
Our Reference: 210121.428C3

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PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

I hereby certify that on the date specified below, this correspondence is being deposited with the United States Postal Service as first-class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, DC 20231.

April 30, 2001 — Sharon Sheridan
Date

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Jiangchun Xu and Davin C. Dillon
Application No.	:	09/030,606
Filed	:	February 25, 1998
For	:	COMPOUNDS FOR IMMUNODIAGNOSIS OF PROSTATE CANCER AND METHODS FOR THEIR USE

Examiner	:	Minh Tam
Art Unit	:	1642
Docket No.	:	210121.428C3
Date	:	March 25, 2001

Commissioner for Patents
Washington, DC 20231

COMMUNICATION TO THE EXAMINER

Dear Sir:

In a telephone conference with the applicants' representatives on March 22, 2001, the Examiner indicated that, while she would be willing to allow claims to methods of detecting prostate cancer using oligonucleotides specific for SEQ ID NO:111 (referred to as N1-1862), she would not be willing to allow claims to methods employing oligonucleotides specific for SEQ ID NO:110, 115, 172-175, 177, 223 or 224, since applicants have not demonstrated over-expression of these sequences in prostate tumor tissue compared to normal prostate tissue.

As stated in the Amendment and Reply filed March 29, 2000, and the Amendment and Reply filed January 2, 2001, it is the applicants' position that it is not necessary for a sequence to be prostate-tumor specific in order for it to be useful in the diagnosis of prostate cancer. As evidenced, by the attached declaration of Dr. Davin Dillon, prostate cells are only able to enter the blood stream when an individual is inflicted with prostate cancer. Thus it is sufficient for a sequence to be prostate-specific in order for it to be effectively employed in the diagnosis of prostate cancer. Applicants' position is further supported by the attached declaration of Dr. Raymond Houghton, which describes studies determining the expression levels of the antigen P501S (SEQ ID NO:110) in blood samples from prostate cancer patients and from normal donors, and the expression levels of the antigen P703P in blood from SCID mice transplanted with prostate tumor and from normal mice. SEQ ID NO:172-175 and 177 represent splice variants of P703P. As stated in the declaration, significantly higher levels of P501S were found in blood from prostate cancer patients compared to normal donors. Similarly, expression of P703P was observed in blood obtained from the SCID mice but not in blood from the control mouse. These results clearly support the applicants' position that prostate-specific sequences may be usefully employed in the detection of prostate cancer.

The specification clearly states on page 29, lines 14-19, that the antigens of SEQ ID NO: 223 and 224 (referred to as P509S and P510S) were found to be over-expressed in prostate tumor and normal prostate compared to all other normal tissues tested as determined by microarray technology. Similarly, using real-time PCR, Northern analysis and micro-array technology, SEQ ID NO:110 and 111 were found to be expressed at significantly higher levels in prostate tumor and normal prostate compared to other normal tissues tested (see Example 2, page 29, line 26-page 32, line 2). It is urged that one of skill in the art to which the present invention pertains, on being provided with the instant specification, would clearly be able to employ oligonucleotides specific for SEQ ID NO:110, 11, 115, 173-175, 177, 223 and 224 to diagnose the presence of prostate cancer and that the rejections of the claims under 35 USC §101 and under 35 USC §112, first paragraph, may be properly withdrawn.

Favorable reconsideration and allowance of all the pending claims is respectfully requested. Should the Examiner have any further concerns regarding the pending claims, she is respectfully requested to telephone the applicants' representative.

Respectfully submitted,

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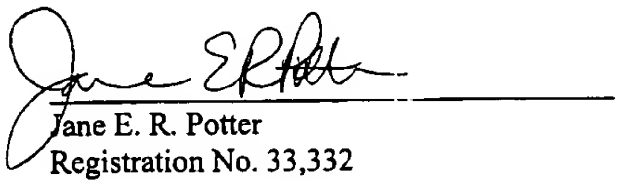

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